

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	MDL No 3026
This Document Relates to: <i>Brown, et al. v. Abbott Laboratories, et al.</i>, Case No 1:22-cv-02001	Master Docket No. 1:22-cv-00071 Hon. Rebecca R. Pallmeyer
PLC's Response to Defendant's Amended Expert Report of Dr. Makuch (ECF No. 693)	

I. Introduction

The PLC responds to the Court’s request regarding the use, if any, of Dr. Makuch’s Amended Expert Report (ECF No. 693) (Supplemental Report). The PLC responds to the Court’s Order from the narrowest possible interpretation (i.e., whether the Supplemental Report may be used in *Brown v. Abbott Nutrition* versus whether it may be used in future Bellwether cases). For purposes of whether it may be used in *Brown* the answer is no. The Court should, for purposes of the *Brown* trial, exclude the Report because (1) it is untimely and prejudicial; (2) there is a proper time and place for this Supplemental Report to be considered, but it is not in *Brown*; and (3) the Court got it right the first time—its ruling to exclude Dr. Makuch should stand.

The procedural history leading to Dr. Makuch’s Supplemental Report is as follows:

- Dr. Makuch served his original report on November 1, 2024.
- The PLC deposed Dr. Makuch on January 17, 2025.
- On February 14, 2025 (ECF No. 612), the PLC moved to exclude Dr. Makuch’s testimony based in part on an inability to justify his opinion that exposure to a toxin must be predicated upon a time period predating the initial exposure (i.e., the 75/25 argument).
- On August 15, 2025 (ECF No. 683), the Court entered its Order excluding Dr. Makuch based on his 75/25 theory but offered Defendant the opportunity to supplement the report in an effort to justify his opinion.
- Rather than supplement his original report, Defendants instead filed a letter brief with the Court on August 21, 2025 (ECF No. 686) contending the Court erred in its analysis and urging the Court to reconsider its prior ruling.
- Twelve days later, on September 2, 2025, the Court issued its Minute Order rejecting Defendant’s letter brief noting, “The court nevertheless stands by its conclusion that Dr. Makuch, who examined studies limited to premature infants who consumed more than 75% human milk, *should supplement his report* with an explanation of why looking at an infant’s entire feeding, as opposed to a more targeted range suggested by Plaintiffs, is the appropriate method of measuring an infant’s exposure to formula.” ECF No. 685, PageID #30077 (emphasis added).

- In response to that Order, on September 12, 2025 (ECF No. 693), nearly a month after the Court allowed Defendant to supplement Dr. Makuch's report, and a mere twelve days before Plaintiff's Opposition to Defendant's Motion to Exclude Dr. Spector was due, Abbott served the PLC with Dr. Makuch's 26-page Supplemental Report, comprised of some 15 exhibits. Defendant did not offer the PLC the opportunity to depose Dr. Makuch (an offer the PLC extended to Defendants with respect to Dr. Spector's Supplemental Report). Specifically, on September 24, 2025, the PLC wrote Defense Counsel inquiring whether they would produce Dr. Makuch for deposition. Defendant originally offered October 7–9—a mere two weeks from the PLC's request, almost two weeks after the due date for the PLC's opposition to Abbott's motion to exclude Dr. Spector was due, and a mere week before the *Daubert* hearing.¹
- The next day, the PLC wrote Defense Counsel indicating those dates were unacceptable and that it would supply Defendant with proposed times to take the deposition.² In response, Defendant wrote the PLC four days later (on September 29, 2025) providing additional dates, the earliest of which predated the *Daubert* hearing in *Brown* by only four days.³

Simply stated, there was insufficient time to prepare for, travel to, and take Dr. Makuch's deposition on his Supplemental Report prior to either the *Daubert* briefing or oral argument.

The delay in producing the Supplemental Report not only impacted the *Daubert* process but also threatens unfair impact on the *Brown* trial. The trial is slated to start on November 3, 2025—exactly one month after the filing of this response. ECF No. 562. The Court has already excluded Dr. Makuch's opinions. ECF No. 683. And despite Abbott's attempt to unwind that dispositive ruling in its August 21, 2025 letter (ECF No. 686), the Court “[stood] by its conclusion” that Dr. Makuch's testimony is inadmissible. ECF No. 685.

¹ See Email from Rebecca Fitzpatrick to Tim Becker, dated September 24, 2025, attached to Declaration of Tim Becker (Becker Decl.) as Exhibit A.

² As set forth in the Becker Decl., Mr. Becker took Dr. Makuch's original deposition and was the obvious choice to take his deposition on the Supplemental Report. But between September 24 (the day of Defendant's first email proposing deposition dates) and October 9, 2025 (the last day Defendant proposed for Dr. Makuch's deposition prior to the *Daubert* hearing), Mr. Becker was unavailable. He had conflicts on September 24–25 (a multi-counsel in-person working meeting which had been calendared for several months), September 29 (a mediation in a separate MDL), October 2–3 (familial conflicts), and October 6–7 (an in-person case management conference in a separate MDL). In short, given multiple pre-existing conflicts, there was not ample time to prepare for, travel to, and attend Dr. Makuch's deposition in the limited window that was offered.

³ See Email from Rebecca Fitzpatrick to Tim Becker, dated September 29, 2025, attached to Becker Decl. as Exhibit B.

Accepting Dr. Makuch's Supplemental Report at the eleventh hour is clearly prejudicial to Ms. Etienne. Trial is imminent. And it was not until the Court excluded Dr. Makuch and suggested Abbott file a supplemental report that Abbott even considered doing so. The 75/25 exposure argument has been front and center in this litigation; it can hardly be suggested that it is a new issue. Simply stated, the time to address it for *Brown* has long passed. And Abbott recognizes that—it advanced the same argument the PLC advances here with respect to Dr. Spector before the *Diggs* trial, contending that the PLC “can try again in a different bellwether to try something different and we’ll be back up here arguing those issues.” No. 1:22-cv-05356 (Hrg. Tr., July 28, 2025,) at 27:25–28:2. The Court agreed with Abbott, refusing to allow Dr. Spector to supplement his report in *Diggs* with trial so quickly approaching. The Court should do the same here.

Plaintiff does not argue Dr. Makuch's Supplemental Report should never be considered by the Court. There is an appropriate time and place to address it, but it is not in *Brown*. The proposed Wave II Bellwether Protocol expressly contemplates supplementation of current expert reports, as well as the submission of new expert reports altogether. Wave II is therefore the most logical and fair time for Dr. Makuch to supplement his report. A supplement should not be permitted before then.

A. Supplementation of an expert report at this stage is both untimely and prejudicial.

Filing a Supplemental Report some 11 months past the discovery deadline for expert reports in this wave of bellwether cases is the epitome of prejudice to the opposing party. ECF No. 562. Despite the Court's suggestion to Abbott to supplement, the fact that the Supplemental Report is untimely remains unwaveringly true. And, as here, “where a party does not timely file expert reports, the district court may exclude the party's expert from testifying at trial” *Finnall v. City of Chicago*, 239 F.R.D. 494, 498 (N.D. Ill. 2006), *objections overruled*, 239 F.R.D. 504 (N.D. Ill. 2006).

But the general untimeliness of this supplement (though it is prejudicial) is not what makes this so overwhelmingly prejudicial. Rather, it is the time relative to the PLC's *Daubert* oppositions and

to trial. The work required to be undertaken to prepare, properly vet, and adequately respond to Dr. Makuch's Supplemental Report while simultaneously briefing *Daubert*, preparing for oral argument and starting trial cannot be completed in this limited time frame. This distinction makes all the difference, as it would be "inappropriate" for Abbott to provide a supplemental expert report at the eleventh hour such that the "other side could neither depose the expert nor engage a rebuttal expert of its own." *Id.* at 499.⁴

Nor is this situation similar to that of Dr. Spector, who submitted an amended expert report after the discovery deadline. Several key facts distinguish that situation from this one. For example:

- 1) The PLC produced Dr. Spector's supplemental report immediately following his first deposition.
- 2) At the same time, the PLC immediately offered Defendants (both Abbott and Mead) a second deposition of Dr. Spector.
- 3) Dr. Spector's supplemental report and both of his depositions were done four months before the start of the first bellwether trial, two months before Rule 702 and Summary Judgment oral arguments, and before the first briefing deadline.⁵

In other words, unlike here, Abbott had plenty of time to consult their experts about Dr. Spector's amended report, depose Dr. Spector a second time, address such issues in its Rule 702 motions and oppositions, prepare for oral argument, and formulate its trial strategy because trial was not

⁴ In *Finnvall*, trial was not imminent. Rather, expert reports were simply filed too near the close of discovery. The Court still excluded the reports. 239 F.R.D. at 498–99.

⁵ Dr. Spector's original deposition was taken on December 23, 2024. Following that, a Supplemental Report was provided on January 16, 2025. And a second deposition was taken on January 31, 2025. The first bellwether trial (*Mar*) was set to begin on May 5, 2025. Oral arguments for Rule 702 and Summary Judgment took place on March 31, 2025. Corresponding motions were filed by defense on February 7, 2025.

imminent—a clear line of demarcation among Courts.⁶ There was no prejudice to Abbott when Dr. Spector provided his amended report. But there is prejudice to Ms. Etienne here.

Abbott had plenty of time to provide the PLC and the Court with a supplement to Dr. Makuch’s original report well before this juncture. It waited nearly a month (after taking the time to push back on the ruling excluding Dr. Makuch through a letter to the Court) to produce the Supplemental Report (eight business days before the PLC’s *Daubert* opposition was due). The 75/25 theory is not a novel issue. It was first argued during the general causation *Daubert* hearing on March 31, 2025—six months ago. The only reason the Supplemental Report was created is because Dr. Makuch was excluded and Abbott’s failure to timely supplement the record in *Brown* eliminates its ability to advance its “total feed” argument to exclude Dr. Spector (an argument this Court twice rejected). No. 1:22-cv-00232, ECF No. 105 (Order), PageID #11072–73. For example, *nothing* stopped Abbott from filing a supplemental report following Dr. Makuch’s deposition, where it became readily apparent his “theory” was predicated on little more than conjecture—a contention with which the Court agreed. ECF No. 683, PageID #30047 (“Dr. Makuch’s report and deposition testimony do not yet meet this burden.”).

Beyond those observations, the Court need look no further than *Abbott’s* argument regarding supplementation of Dr. Spector’s report to evidence that allowing the Supplemental Report is prejudicial. Abbott argued Dr. Spector’s supplementation in *Diggs* was patently prejudicial, given “[Dr. Spector] has had every chance to address this issue for literally two -- over two years, and he hasn’t

⁶ In *Miller UK Ltd.*, the Court declined to exclude a supplemental expert opinion because the supplementation was submitted two weeks after the submission of the original report and more than 6 months before the beginning of trial. The supplement did not prevent the opposing party from preparing its defense, nor was the subject opinion disclosed on the eve of trial, so there was more than enough time to adjust a litigation strategy. *Miller UK Ltd. v. Caterpillar, Inc.*, No. 10-CV-03770, 2015 WL 10818831, at *5 (N.D. Ill. Nov. 1, 2015). In contrast, here, trial is 30 days away, the Court has already excluded Dr. Makuch’s opinion, and Ms. Etienne has relied on that exclusion in crafting her litigation strategy.

done it” until now. No. 1:22-cv-05356, ECF No. 109 (Hrg Tr., July 28, 2025) at 7:12–14. As in *Diggs*, Dr. Makuch had “every chance” to address the 75/25 issue and has not done so until now. And as in *Diggs*, Ms. Etienne “would need to have a fair opportunity to respond [to the supplemental report]. And that would mean, [the PLC would] have to have [its] own experts address it, have to take his depo first.” *Id.* at 7:24–8:1. Given the timetable in this case, Ms. Etienne will not have an opportunity to do so.

The issue here is not just the untimely nature of the Supplemental Report, but the prejudice it will cause Ms. Etienne due to the imminence of trial. As Abbott argued in *Diggs*, “it is fundamentally unfair” (*Id.* at 8:12–17) to allow this type of supplemental analysis at the last minute, especially given “how apparent this issue was and how front and center this issue has been, and it has never been addressed.” *Id.* at 8:3–6. As in *Diggs*, Abbott has had nearly a year to fix the deficiencies in the 75/25 theory and *chose* not to do so. Abbott may claim that was because it believed it would win the 75/25 argument. But Ms. Diggs believed the same about Dr. Spector, and that argument was insufficient to afford her the opportunity to supplement Dr. Spector’s report. The result should be the same here. As such, the PLC requests the Court exclude Dr. Makuch in *Brown*. Should Abbott opt to pursue the 75/25 theory in a subsequent Bellwether case, the PLC has no objection to a supplemental report from Dr. Makuch so long as it is timely provided.

B. The proper time and place to address the Supplemental Report of Dr. Makuch is in the next wave of bellwether cases.

The appropriate time and place to address Dr. Makuch’s Supplemental Report is in the next wave of bellwether cases. *Brown* is the last Abbott case in the first round of bellwether trials. Expert report deadlines were almost one year ago, general-causation expert depositions were completed more than six months ago, general-causation Rule 702 oral arguments were heard more than five months ago, and the start of the *Brown* trial is in 30 days. It was not until September 12, 2025, that Abbott finally took the steps to attempt to resolve the deficiency in Dr. Makuch’s expert report. The Court

previously excluded Dr. Makuch in this wave of bellwethers—and unlike Dr. Spector’s supplemental report, where Defendants were afforded the right to depose him for a second time before filing their Rule 702 motion, there is no opportunity to do so here without seriously delaying the trial (a proposition this Court rejected in *Diggs*). In other words, the right time to supplement an expert report is not while trial is imminent. But that is not to say there is no right time.

The PLC’s argument is not that Dr. Makuch’s Supplemental Report should be permanently barred from this litigation. Rather, the PLC’s position is the Supplemental Report should be addressed in the next wave of bellwethers, where the PLC will have a full and fair opportunity to address Dr. Makuch’s new and evolving theory. And the proposed Wave II Bellwether Protocol expressly permits supplementation of preexisting reports.⁷ Wave II is the right time to supplement the report—not now.

C. The Court got it right the first time in its ruling to exclude Dr. Makuch

Whether or not Dr. Makuch’s Supplemental Report will move the Court (which it should not) remains to be seen. But an initial (and extremely preliminary) review, absent any testimony from Dr. Makuch himself, suggests the Court reached the correct conclusion in excluding Dr. Makuch when it ruled:

Dr. Makuch “has no opinion on [infants] in whom the human milk threshold was less than 75 percent,” and reviewed no studies where a group of infants in any study received more than 30% formula. And even if the court were to include that the proper measure of D.B.’s intake of CMBF would show he received more than 30%, Dr. Makuch’s meta-analysis may not help a jury determine whether CMBF did or did not have a causal effect.

ECF No. 683, PageID #30046. The Report is littered with inconsistencies from his prior deposition, inaccurately characterizes the literature, and makes statements he is unqualified to make.

⁷ While the Wave II bellwether discovery protocol has not been finalized, Plaintiffs contend it will be more lenient toward both amendments to expert reports and/or new expert reports altogether.

1. Newfound Scientific Understanding

Citing Liu et al. 2023, Dr. Makuch argues, “that ‘human milk growth factors could regulate gut barrier integrity and microbial colonization.’ It thus makes sense from a physiological standpoint to examine the amount of human milk fed from birth or throughout the entire NICU stay, rather than some limited range in the days or hours immediately preceding a NEC diagnosis.” ECF No. 693-2 (Makuch Supp. Rep.), PageID #30289. But by his *own admission* Dr. Makuch does not have a clue what any of this means. Becker Decl. Ex. C (Makuch Tr.) at 38:9–20; 45:20–24; 63:20–64:2; 194:21–195:5; 222:10–18. He is not a doctor, is not board-certified in *anything*, cannot treat *anyone*, and has no experience with NEC. *Id.* at 21:5–14; 22:9–11; 63:20–64:2; 106:7–13; 230:18–25; ECF No. 693-2, PageID #30300–26. In fact, his knowledge of NEC is so lacking he denied knowing what fulminant NEC is—the exact disease that killed D.B. *Id.* at 64:3–25. The contention that he is now able to support his Supplemental Report through his understanding of the “physiology” of premature infants does not pass muster.

2. Reliance on Dr. Martin

Dr. Makuch, in a statement diametrically opposed to that above, states, “I rely on Dr. Camila Martin, who explains that the protections of human milk are lasting.” ECF No. 693-2, PageID #30288. Apparently, on the one hand, Dr. Makuch is now an expert in human physiology, while on the other he acknowledges he must rely on Dr. Martin (Abbott’s actual neonatologist) to understand the “protective effects” of human milk. But as noted in the PLC’s opposition to Abbott’s Motion to Exclude Dr. Spector, Dr. Martin *has no idea* how much milk is required to be protective, how long the protection lasts, or whether that protection can overcome a sudden and immediate shift to a predominantly formula diet like that in *Brown*. ECF No. 696. Nothing in the Supplemental Report remotely endeavors to address these facts. Reliance on an expert whose testimony amounts to speculation is little more than speculation itself.

3. Sullivan et al. Undermines His Theory

Once again, Dr. Makuch endorses the findings from Sullivan et al. *Id.* at 30284. Sullivan reported that the risk of NEC from exposure to CMBF was $RR=2.75$ (CI: 1.16–6.52)—i.e., a statistically significant study. As noted in the Spector opposition, Sullivan reported that the median percentage of mother’s own milk in the bovine arm was 82% (meaning the median percent of consumed CMBF was 18%). ECF No. 696. But the range of fortifier on a percentage basis in the bovine arm was 0–62%. *Id.* In other words, there were infants in the bovine arm that received the same amount of cow’s-milk-based formula (albeit in the form of fortifier—a far less toxic concoction) as D.B. did. Dr. Makuch’s Supplemental Report is utterly silent on this fact.

4. Pivot from Prior Studies

In his original deposition, Dr. Makuch repeatedly disavowed relying on Meinzen-Derr 2009 (a dose-response study reporting infants fed 50% formula diets had a statistically significant increased risk of establishing NEC). But in his prior deposition, Dr. Makuch, in a rare moment of candor, admitted the following:

- Q. Was it your opinion that Meinzen-Derr [which found a dose response at a 50/50 feeding protocol] supported your analysis of this 75-25 percent threshold?
- A. I don’t know if it supported the analysis.

Becker Decl. Ex. C (Makuch Tr.) at 113:10–14. He went on to expressly disavow that Meinzen-Derr supported the 75/25 theory. *Id.* at 113:21–114:–2.⁸ And, in fact, he ultimately rejected Meinzen-Derr as supportive of his study. *Id.* at 128:8–11 (“Q: And that’s because you believe that that type of threshold [72/25%] is reported in this study [Meinzen-Derr]; right? A. I disagree.”). Equally important—and never resolved by Dr. Makuch in either his deposition or Supplemental Report—the

⁸ “Q: First, just to put it in your parlance, Meinzen-Derr was a like-to-like type study that supported your 75-25 percent threshold; right? Mr. Hogan: Objection to form. A: ***Not that I recall. That wasn’t the reason that I recall.***”

Methods section of the study stated: “The temporal relationship between early feeding and NEC or death is extremely important.” *Id.* at 121:13–15. Simply put, the study acknowledged that *temporality* of the onset of formula feeding to NEC is “extremely important,” which is why Dr. Makuch spent dozens of pages endeavoring to unhinge himself from the study. But today, his Supplemental Report makes a radical U-turn, now repeatedly endorsing the study’s findings because it reported feeding rates that were higher than those D.B. received. ECF No. 693-2, PageID #30283, n.17. Whatever his rationale will be for this radical departure, it is a far cry from scientific rigor.

How Dr. Makuch will address his newfound positions—some of which are diametrically opposed to his prior testimony—will be interesting. But for now, these inconsistencies are relevant to the extent they signal the need to explore the radical departures from his prior positions. As such, the PLC must be given an opportunity to address the inconsistencies noted above, along with scores of others. To date, it has not been afforded an adequate opportunity to do. Nor can Abbott save Dr. Makuch in *Brown* through its inevitable argument that the PLC’s interpretation of his Supplemental Report is wrong. ECF No. 686, PageID #30079. Dr. Makuch—and not Abbott’s counsel—must stand by his work and defend the radical departure from his prior opinion, a task he will be hard-pressed to do.

Ultimately, Dr. Makuch’s total-feed construct is not viable. It was not viable before the Supplemental Report, and it is not viable now. As the PLC argued in its Opposition to Exclude Dr. Spector, exposure to formula can only be measured from when an infant is first fed formula. To argue otherwise would sidestep logic—measuring formula exposure before the exposure ever occurred. ECF No. 696, PageID #30531–32. And in the days following exposure to CMBF, D.B.’s intake of CMBF was far more than 25%. Regardless of whether or not the Court accepts or rejects the PLC’s position, no decision based on his Supplemental Report can occur until the PLC has an opportunity to fully and fairly explore the scope of Dr. Makuch’s newfound theory and application of the

literature—something to date it has not had the opportunity to do given Abbott’s untimely production. The Supplemental Report should be excluded from the *Brown* trial.

II. Conclusion

In light of the untimeliness and prejudice to Plaintiffs in the filing of the Dr. Makuch’s Supplemental Report, it should not be considered in *Brown*. The appropriate time to address the supplementation is in the next round of bellwether cases. Plaintiff respectfully requests the Amended Report for Dr. Makuch be excluded at this time and the Court’s prior ruling on exclusion to stand.

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Respectfully submitted,

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